UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF TENNESSEE
KNOXVILLE DIVISION

BARBARA C. RADFORD,	)	
	)	
Plaintiff	)	Jury Trial Demanded
	)	
v.	)	CIVIL ACTION
	)	FILE NO. _____
COOK INCORPORATED;	)	
COOK MEDICAL, LLC f/k/a	)	
COOK MEDICAL	)	
INCORPORATED; and	)	
COOK GROUP INCORPORATED	)	
	)	
Defendants.	)	

COMPLAINT AND DEMAND FOR JURY TRIAL

Plaintiff, BARBARA C. RADFORD (hereinafter "Plaintiff"), by and through her attorneys, hereby files, Plaintiff's Complaint and Demand for Jury Trial, against Defendants COOK INCORPORATED, COOK MEDICAL LLC f/k/a COOK MEDICAL INCORPORATED; and COOK GROUP INCORPORATED (hereinafter "Cook Defendants" or "Cook"), and alleges the following:

1. There is an action for damages relating to Defendants' development, testing, assembling, manufacture, packaging, labeling, preparing, distribution, marketing, supplying, and/or selling defective products sold under the name "inferior vena cava filter" (hereinafter "IVC filter").

2. Cook IVC Filters are associated with, and cause, an increased risk for serious injury and death as a result of adverse events including: tilting, perforation, fracture, breakage and migration.

3. At all times relevant to this action, Cook intentionally, recklessly, and/or negligently failed to act as to the known failures and injuries associated with its devices and/or failed to warn about

and concealed, suppressed, omitted, and/or misrepresented the risks, dangers, defects, and disadvantages of its IVC filters.

4. At all times relevant to this action, Cook intentionally, recklessly, and/or negligently advertised, labeled, promoted, marketed, sold and/or distributed its IVC Filters as a safe medical device when in fact Cook knew and/or had reason to know, that its IVC Filters were not safe for its intended purposes, and that its IVC Filters caused serious injury and death.

5. At all times relevant to this action, Cook is and was strictly liable for injuries caused by its IVC Filters because the devices are unreasonably dangerous and not accompanied by adequate warnings about its danger.

PARTIES

6. Plaintiff, BARBARA C. RADFORD, at all times relevant to this action was a citizen and resident of Union County in the State of Tennessee.

7. Defendant, Cook Incorporated, is an Indiana Corporation with its principal place of business located at: 750 Daniels Way, P.O. Box 489, Bloomington, Indiana 47402. Defendant, Cook Incorporated, is authorized and/or doing business in the State of Tennessee, including Union County. At all times relevant to this action, Cook Incorporated designed, set specifications, manufactured, prepared, compounded, assembled, processed, promoted, marketed, distributed and/or sold its inferior vena cava filters ("IVC Filters") to be implanted in patients throughout the United States, including Tennessee. At all times relevant hereto, Defendant Cook Incorporated, was engaged in business in Tennessee, has conducted substantial business activities, and derived substantial revenue from within the State of Tennessee. Defendant has also carried on solicitations or service activities in Tennessee. The registered agent for Cook Incorporated is Corporation Service Company, 135 North Pennsylvania Street, Suite 1610, Indianapolis, IN 46204. Cook Incorporated may be served with process by delivering a

Summons with a copy of this Complaint attached thereto to its registered agent.

8. On information and belief, Cook Incorporated is a privately-owned corporation with wholly owned subsidiaries that it controlled, including Cook Medical, LLC f/k/a Cook Medical Incorporated, and Cook Group Incorporated.

9. Defendant, Cook Medical, LLC, is a privately-owned Indiana limited liability company with its principal place of business located at: 1025 West Acuff Road, Bloomington, Indiana 47404. Cook Medical, LLC was formerly known as Cook Medical Incorporated. Cook Medical, LLC is doing business in the state of Tennessee, including Union County. At all times relevant to this action, Cook Medical, LLC designed, set specifications, manufactured, prepared, compounded, assembled, processed, promoted, marketed, distributed and/or sold its IVC Filters to be implanted in patients throughout the United States, including Tennessee. At all times relevant hereto, Defendant, Cook Medical, LLC was engaged in business in Tennessee, has conducted substantial business activities, and derived substantial revenue from within the State of Tennessee. Defendant has also carried on solicitations or service activities in Tennessee. The registered agent for Cook Medical, LLC is: Corporation Service Company, 135 North Pennsylvania Street, Suite 1610, Indianapolis, IN 46204. Cook Medical, LLC may be served with process by delivering a Summons with a copy of this Complaint attached thereto, to its registered agent.

10. Defendant, Cook Group Incorporated, is an Indiana Corporation with its principal place of business located at: 750 Daniels Way, P.O. Box 489, Bloomington, Indiana 47402. Defendant, Cook Group Incorporated, is doing business in the State of Tennessee, including Union County. At all times relevant to this action, Cook Group Incorporated designed, set specifications for, manufactured, prepared, compounded, assembled, processed, promoted, marketed, distributed, and sold its IVC Filters to be implanted in patients throughout the United States, including Tennessee. At all times relevant

hereto, Defendant, Cook Group Incorporated, was engaged in business, has conducted substantial business activities, and derived substantial revenue from within the State of Tennessee. Defendant has also carried on solicitations or service activities in Tennessee. The registered agent for Cook Group Incorporated is: Corporation Service Company, 135 North Pennsylvania Street, Suite 1610, Indianapolis, IN 46204. Cook Medical Incorporated may be served with process by delivering a Summons with a copy of this Complaint attached thereto, to its registered agent.

11. Defendants Cook Incorporated, Cook Medical, LLC f/k/a Cook Medical Incorporated, and Cook Group Incorporated are hereinafter collectively referred to as "Cook Defendants" or "Cook."

12. At all relevant times, the Cook Defendants were in the business of designing, setting specifications for, manufacturing, preparing, compounding, assembling, processing, marketing, packaging, and selling its IVC filters to distributors and sellers, including hospitals, for implantation by physicians at hospitals in patients throughout the United States, including in Tennessee.

13. At all relevant times, each of the Cook Defendants regularly marketed, distributed, and sold its IVC filters throughout Tennessee and sold its IVC filters in Tennessee for resale and implantation into human patients, including Plaintiff.

14. At all relevant times, each of the Cook Defendants and their directors and officers acted within the scope of their authority. At all relevant times each Cook defendant was responsible for each other's actions and inactions; and each Cook defendant acted on behalf of each other Cook defendant.

15. At all relevant times, the Cook Defendants possessed a unity of interest between themselves and Cook. Cook exercised control over its subsidiaries and affiliates. As such, each Cook Defendant is responsible jointly and severally to Plaintiff for her injuries, losses, and damages.

JURISDICTION AND VENUE

16. This is a lawsuit for personal injury damages in excess of $75,000.00. There is complete diversity of citizenship between Plaintiff and the Defendants as the parties are citizens/entities of different states. Accordingly, subject matter jurisdiction in proper in this Court pursuant to 28 U.S.C. 1332. Further, this Court has personal jurisdiction over the Defendants because they have done business in the State of Tennessee, have committed a tort in whole or in part in the State of Tennessee, have substantial and continuing contact with the State of Tennessee, and derive substantial revenue from goods used and consumed within the State of Tennessee. The Defendants actively sell, market, and promote their product to physicians and consumers in this state on a regular and consistent basis. Such activities include, but are not limited to: (a) sales of IVC filters, including the Cook filter at issue in this case, in this jurisdiction; (b) hiring, training, and deploying employees, including managers and sales representatives, in this jurisdiction; (c) advertising and marketing of their IVC filters, including the Cook filter at issue in this case, in this jurisdiction; (d) maintenance of company files and equipment relating to the Cook filter in this case, in this jurisdiction; (e) payment of employee salaries in this jurisdiction; and (f) maintenance of a website directed to all states, including Tennessee. The Cook Defendants also committed tortious acts within the State of Tennessee and caused injury to persons or property within the State of Tennessee arising out of acts or omissions by the Cook Defendant outside this state at or about the time of the Plaintiff's injury, while the Cook Defendants were engaged in solicitation or service activities within the State of Tennessee; and/or, while products, materials, or things processed, serviced, or manufactured by the Cook Defendants were used or consumed within the State of Tennessee in the ordinary course of commerce, trade, or use.

17. Defendants are subject to *in personam* in the U.S. District Court for the Eastern District of Tennessee because they placed a defective product in the stream of commerce and that product caused

personal injuries to Plaintiff in Tennessee. Further, venue is proper in this jurisdiction pursuant to 28 U.S.C. § 1391, because a substantial part of the events or omissions giving rise to the claim occurred in this District, and because Defendants conduct substantial business in this District.

FACTUAL BACKGROUND

INFERIOR VENA CAVA FILTER IN GENERAL

18. IVC filters were first made commercially available to the medical community in the 1960s. Over the years, medical device manufacturers have introduced several different designs of IVC filters.

19. An IVC filter is a device that is designed to filter or "catch" blood clots that travel from the lower portions of the body to the heart and lungs. IVC filters were originally designed to be permanently implanted in the IVC.

20. The IVC is a vein that returns blood to the heart from the lower portions of the body. In certain people, for various reasons, blood clots travel from the vessels in the legs and pelvis, through the vena cava and into the lungs. Oftentimes, these blood clots develop in the deep leg veins, a condition called "deep vein thrombosis" or "DVT." Once blood clots reach the lungs, they are considered "pulmonary emboli" or "PE." Pulmonary emboli present risks to the human health.

21. People at risk for DVT/PE can undergo medical treatment to manage the risk. For example, a doctor may prescribe anticoagulant therapies such as medications like Heparin, Warfarin, or Lovenox to regulate the clotting factor of the blood. In some people who are at high risk for DVT/PE and who cannot manage their conditions with medications, physicians may recommend surgically implanting an IVC filter to prevent thromboembolitic events.

22. As stated above, IVC filters have been on the market for decades and were permanent implants. However, use of these filters was limited primarily to patients who were contraindicated for anticoagulation therapy.

23. Other manufacturers also saw their opportunity triggering a race to market a device that provided physicians the option to retrieve the filter after the clot risk subsided.

COOK INFERIOR VENA CAVA FILTERS GENERALLY

24. Defendants design, research, develop, manufacturer, test, market, advertise, promote, distribute, and sell products that are sold to and marketed to prevent, among other things, recurrent pulmonary embolism via placement in the vena cava. Defendants' product**s** include, the Cook Celect® Vena Cava Filter, and the Gunther Tulip® Filter (collectively referred to herein as "Cook Filters"), which are introduced via a coaxial introducer sheath system.

25. Defendants sought Food and Drug Administration ("FDA") approval to market the Cook Filters and/or its components under Section 510(k) of the Medical Device Amendment.

26. Section 510(k) allows marketing of medical devices if the device is substantially equivalent to other legally marketed predicate devices without formal review for the safety or efficacy of the said device. The FDA explained the difference between the 510(k) process and the more rigorous "premarket approval" process in an amicus brief filed with the Third Circuit in *Horn v. Thoratec Corp*., 376 F.3d 163, 167 (3d Cir. 2004):

> A manufacturer can obtain an FDA finding of "substantial equivalence" by submitting a premarket notification to the agency in accordance with section 510(k)…A device found to be 'substantially equivalent' to a predicate device is said to be "cleared" by FDA (as opposed to "approved" by the agency under a [premarket approval]). A pre-market notification submitted under 510(k) is thus entirely different from a [pre-market approval] which must include data sufficient to demonstrate that the device is safe and effective. (Emphasis in original).

27. In *Medtronic, Inc. v. Lohr*, 518 U.S. 470,478-79 (1996), the Supreme Court similarly described the 510(k) process, observing:

> If the FDA concludes on the basis of the [manufacturer's] §510(k) notification that the device is 'substantially equivalent' to a pre-existing device, it can be marketed without further regulatory analysis…The §510(k) notification process is by no means comparable to the [premarket approval] process; in contract to the 1,200 hours necessary to complete a PMA review, the §510(k) review is completed in average of 20 hours…Section §510(k) notification requires little information, rarely elicits a negative response from the FDA, and gets process quickly.

28. An IVC filter, like the Cook Filters, is a device designed to filter blood clots (called "thrombi") that travel from the lower portions of the body to the heart and lungs. IVC filters may be designed to be implanted, either temporarily or permanently, within the vena cava.

29. The inferior vena cava is a vein that returns blood to the heart from the lower portion of the body. In certain people, and for various reasons, thrombi travel from vessels in the legs and pelvis, through the vena cava into the lungs. Often these thrombi develop in the deep leg veins. The thrombi are called "deep vein thrombosis" or DVT. Once the thrombi reach the lungs they are considered "pulmonary emboli" or PE. An IVC filter, like the Cook IVC Filters are designed to prevent thromboembolic events.

30. The Cook Filters are retrievable filters.

31. The Cook Celect® Vena Cava Filter has four (4) anchoring struts for fixation and eight (8) independent secondary struts to improve self-centering and clot trapping.

32. The Gunther Tulip® Vena Cava Filter has a top hook and (4) anchoring struts for

fixation and on each strut, it has a "flower" formation that is shorter than the strut where a wire piece branches out on each side of the strut forming an overall "flower" type formation on each strut.

33. At all times relevant hereto, the Cook Filters were widely advertised and promoted by the Defendants as safe and effective treatment for the prevention of recurrent pulmonary embolism via placement in the vena cava. At all times relevant hereto, Defendants knew its Cook Filters were defective and knew that defect was attributable to the design's failure to withstand the normal anatomical and physiological loading cycles exerted *in vivo.*

34. A retrospective review of all Cook Gunther Tulip® Filters and Cook Celect® filters retrieved between July 2006 and February 2008 was performed. One hundred and thirty (130) filter retrievals were attempted but in 33 cases, the standard retrieval technique failed. The authors concluded that "unsuccessful retrieval was due to significant endothelialization and caval penetration" and that "hook endothelialization is the main factor resulting in failed retrieval and continues to be a limitation with these filters." O. Doody, et al.; "Assessment of Snared-Loop Technique When Standard Retrieval of Inferior Vena Cava Filters Fail" Cardiovasc Intervent Radiol (Sept 4, 2008 Technical Note).

35. A retrospective review of 115 patients who underwent Cook Celect® IVC filter insertion between December 2005 and October 2007 was performed. While filter insertion was successful in all patients, the authors also concluded that "[f]ailed retrieval secondary to hook endothelialization continues to be an issue with this filter." O. Doody, et al; Journal of Medical Imaging and Radiation Oncology "Initial Experience in 115 patients with the retrievable Cook Celect® vena cava filter" 53 (2009) 64-68 (original article).

36. In a review of clinical data related to 73 patients who had Celect® IVC filter implanted between August 2007 and June 2008, the authors found that the Celect® IVC filter were related to

a high incidence of caval filter leg penetration. Immediately after fluoroscopy-guided filter deployment in 61 patients, four filters (6.5%) showed significant tilt. Follow-up abdominal CT in 18 patients demonstrated filter related problems in 7 (39%), which included penetration of filter legs in 4 and fracture/migration of filter components in 1.

37. In a study of Gunther Tulip® and Celect® IVC filters, implanted between July 2007 and May of 2009, reported by Cardiovascular Interventional Radiology electronically on March 30, 2011 and published by journal in April 2012, one hundred percent of the Cook Celect® filters and Gunther Tulip® filters imaged after 71 days of implant caused some degree of filter perforation of the venal caval wall. Durack JC, et al, Cardiovasc Intervent Radiol., "Perforation of the IVC: rule rather than the exception after longer indwelling times for the Gunther Tulip® and Cook Celect® Retrievable Filters," 2012 Apr.; 35(2):299-308. Epub 2011 Mar 30. The authors concluded: "Although infrequently reported in the clinical literature, clinical sequelae from IVC filter components breaching the vena cava can be significant." Defendants knew or should have known that their IVC filters were more likely than not to perforate the vena cava wall.

38. This same study reported that tilt was seen in 20 out of 50 (40%) of the implanted Gunther Tulip® and Celect® IVC filters and all tilted filters also demonstrated vena caval perforation. Defendants knew or should have known that their IVC filters were more likely than not to tilt and to perforate.

39. While not inclusive of all medical studies published during the relevant time period, the above references show that the Defendants failed to disclose to physicians, patients, and/or Plaintiff that its Cook Filters were subject to breakage, tilt, inability of removal, and migration even though they knew or should have known the same was true**.**

40. At all times relevant hereto, the Defendants continued to promote the Cook Filter as

safe and effective even when inadequate clinical trials had been performed to support long or short to safety and/or efficacy.

41. The Defendants concealed the known risks and failed to warn of known or scientifically knowable dangers and risks associated with the Cook Filters, as aforesaid.

42. The Cook Filters are constructed of conichrome.

43. The Defendants specifically advertise the conichrome construction of the filter as a frame which "reduces the risk of fracture."

44. The failure of the Cook Filters is attributable, in part, to the fact that the Cook Filters suffer from a design defect causing it to be unable to withstand the normal anatomical and physiological loading cycles exerted *in vivo.*

45. At all times relevant hereto, the Defendants failed to provide sufficient warnings and instructions that would have put Plaintiff and the general public on notice of the dangers and adverse effects caused by implantation of the Cook Filters, including, but not limited to the design's failure to withstand the normal anatomical and physiological loading cycles exerted *in vivo.*

46. The Cook Filters were designed, manufactured, distributed, sold, and/or supplied by the Defendants, and were marketed while defective due to the inadequate warnings, instructions, labeling, and/or inadequate testing in light of Defendants' knowledge of the products' failure and serious adverse events.

47. That at all times relevant hereto, the officers and/or directors of the Defendants named herein participated in, authorized and/or directed the production and promotion of the aforementioned products when they knew or should have known of the hazardous and dangerous propensities of the said products, and thereby actively participated in the tortious conduct that resulted in the injuries suffered by Plaintiff.

PLAINTIFF'S COOK FILTER AND INJURIES

48. On or about October 18, 2018, Plaintiff, BARBARA C. RADFORD was implanted with a Cook Celect® Vena Cava Filter at Premier Surgical Associates in Knoxville, Tennessee.

49. Plaintiff has undergone multiple computed tomography ("CT") scans of her abdomen and pelvis. The CT scans revealed that the Cook Celect® filter has IVC thrombus above, within, and below the level of the IVC filter.

50. Plaintiff has also suffered from medial filter apex contacting the vena cava and has become embedded into the caval wall preventing removal. All six (6) struts of the filter significantly tent the caval wall with the lateral strut perforating the vena cava wall without significant impingement of any surrounding structures. The anterior strut is suspected of early perforation of the caval wall with direct posterior impingement of the small bowel.

51. Plaintiff is at risk for future Cook Celect® filter fractures, migrations, continued perforations, and impingement on surrounding structures. Plaintiff faces numerous health risks, including the risk of death.

52. For the rest of her life, Plaintiff will require ongoing medical care and monitoring.

53. Plaintiff has also suffered significant, disfiguring injuries, including significant pain, and distress restricting her ability to engage in activities of daily living.

54. Furthermore, Plaintiff has incurred substantial medical expenses, as a result of Cook's defective device, and, on information and belief, she will continue to incur substantial medical expenses in the future.

55. As a result of the implanted IVC filter, Plaintiff has suffered post-implant pulmonary emboli, occluded filter that has caused, collateral veins to form and grow around the occluded filter with decrease blood flow from the lower extremities, perforation of the caval wall, impingement of small

bowel, chest pain, back pain, abdominal pain, numbness in extremities and internal discomfort, continual medical care and monitoring and any other possible symptoms.

COUNT I: STRICT PRODUCTS LIABILITY – FAILURE TO WARN

56. Plaintiff repeats and realleges all previous paragraphs.

57. Cook Filters were defective and unreasonably dangerous when they left the possession of the Defendants in that they contained warnings insufficient to alert consumers, including Plaintiff, of the dangerous risks associated with the subject product, including but not limited to the risk of tilting, perforation, fracture and migration, which are associated with and did cause serious injury and/or death.

58. Information provided by Cook to the medical community and to consumers concerning the safety and efficacy of its Cook Filters did not accurately reflect the serious and potentially fatal adverse events Plaintiff could suffer.

59. At all times relevant hereto, the Cook Filters were dangerous and presented a substantial danger to patients who were implanted with the Cook Filter, and these risks and dangers were known or knowable at the times of distribution and implantation in Plaintiff. Ordinary consumers would not have recognized the potential risks and dangers the Cook Filters posed to patients, because their use was specifically promoted to improve health of such patients.

60. Had adequate warnings and instructions been provided, Plaintiff would not have been implanted with the Cook filter and would not have been at risk of the harmful injuries described herein. The Cook Defendants failed to provide warnings of such risks and dangers to Plaintiff and their medical providers as described herein. Neither Plaintiff, nor Plaintiff's physicians knew, nor could they have learned through the exercise of reasonable care, the risks of serious injury and/or death associated with and/or caused by Cooks' Filters.

61. Cook Defendants knew or had knowledge that the warnings that were given failed to

properly warn of the increased risks of serious injury and/or death associated with and/or caused by Cook Filters.

62. Plaintiff, individually and through her implanting physician, reasonably relied upon the skill, superior knowledge, and judgment of the Cook Defendants.

63. Cook Defendants were under a continuing duty to warn Plaintiff and her physicians of the dangers associated with the filter.

64. Safer alternatives were available that were effective and without risks posed by Cook's Filters.

65. As a direct and proximate result of the Cook Filter's defects, as described herein, Plaintiff suffered permanent and continuous injuries, pain and suffering, disability, and impairment. Plaintiff has suffered emotional trauma, harm, and injuries that will continue into the future. Plaintiff has lost her ability to live a normal life and will continue to be so diminished into the future. Furthermore, Plaintiff has medical bills, both past and future, related to care because of the Cook Filters' defects.

66. By reason of the foregoing, Cook Defendants are liable to Plaintiff for damages as a result of their failure to warn and/or adequately warn the Plaintiff and her healthcare professionals about the increased risk of serious injury and death caused by their defective Cook filters.

67. WHEREFORE, Plaintiff demands judgment against the Cook Defendants and seeks damages, including compensatory damages, exemplary damages, and punitive damages, together with interest, the costs of suit and attorneys' fees, and other such other and further relief as this Court deems just and proper.

COUNT II: STRICT PRODUCTS LIABILITY - MANUFACTURING DEFECT

68. Plaintiff incorporates by reference all prior allegations.

69. Prior to, on, and after the date the Cook Gunther Tulip® IVC Filter was implanted in

Plaintiff, Cook designed, distributed, manufactured, sold, and marketed Cook IVC Filters for use in the United States.

70. At all relevant times, Cook designed, distributed, manufactured, marketed, and sold Cook IVC Filters that were unreasonably dangerous, unsafe, and defective in manufacture when they left Cook's possession.

71. Upon information and belief, Cook IVC Filters contain a manufacturing defect, in that they differed from the manufacturer's design or specifications, defectively manufactured as they failed to comply with their own specifications or from other typical units of the same product line.

72. Upon information and belief, Cook IVC Filters contain a manufacturing defect, in that they failed to contain adequate warnings and are more dangerous than would be contemplated by an ordinary user and also because of the risks of the products outweigh their benefits.

73. As a direct and proximate cause of Cook's design, manufacture, marketing, and sale of Cook IVC Filters prior to, on, and after the date Plaintiff was implanted with the Cook Gunther Tulip® filter, Plaintiff suffered Injuries and Damages.

COUNT III: STRICT PRODUCTS LIABILITY - INFORMATION DEFECT

74. Plaintiff incorporates by reference all prior allegations.

75. At all relevant times, Cook engaged in the business of testing, developing, designing, manufacturing, packaging, labeling, marketing and/or promoting, selling and/or distributing Cook IVC Filters and through that conduct has knowingly and intentionally placed Cook IVC Filters into the stream of commerce with full knowledge that they reach consumers such as Plaintiff who would become implanted with them.

76. Cook did in fact test, develop, design, manufacture, package, label, market and/or promote, sell and/or distribute Cook IVC Filters to Plaintiff, Plaintiff's prescribing health care

professionals, and the consuming public. Additionally, Cook expected that the Cook IVC Filters they were selling, distributing, supplying, manufacturing, and/or promoting to reach, and did in fact reach, prescribing health care professionals and consumers, including Plaintiff and Plaintiff's prescribing health care professionals without any substantial change in the condition of the product from when it was initially distributed by Cook.

77. The Cook IVC Filters had potential risks and side effects that were known or knowable to Cook by the use of scientific inquiry and information available before, at, and after the manufacture, distribution, and sale of the Cook IVC Filters.

78. Cook knew or should have known of the defective condition, characteristics, and risks associated with Cook IVC Filters. These defective conditions included, but were not limited to: (1) Cook IVC Filters posed a significant and higher risk of failure than other similar IVC filters (fracture, migration, tilting, and perforation of the vena cava wall); (2) Cook IVC Filter failures result in serious injuries and death; and (3) certain conditions or post-implant procedures, such as morbid obesity or open abdominal procedures, could affect the safety and integrity of Cook IVC Filters.

79. Cook IVC Filters were in a defective and unsafe condition that was unreasonably and substantially dangerous to any user or consumer implanted with Cook IVC Filters, such as Plaintiff, when used in an intended or reasonably foreseeable way.

80. The warnings and directions Cook provided with Cook IVC Filters failed to adequately warn of the potential risks and side effects of Cook IVC Filters:

a. Defectively Designed because they are more dangerous than would be contemplated by an ordinary user, and also because the risks of the products outweigh their benefits;

b. Defectively Manufactured as they failed to comply with their own specifications.

81. These risks were known or were reasonably scientifically knowable to Cook, but not

known or recognizable to ordinary consumers, such as Plaintiff, or to Plaintiff's treating doctors.

82. Cook IVC Filters were expected to, and did reach Plaintiff without substantial change in their condition, labeling, or warnings as manufactured, distributed, and sold by Cook.

83. Additionally, Plaintiff and Plaintiff's physicians used Cook IVC Filters in the manner in which they were intended to be used, making such use reasonably foreseeable to Cook.

84. As a direct and proximate result of Cook's information defects, lack of sufficient instructions or warnings prior to, on and after the date Plaintiff was implanted with the Cook Gunther Tulip® Filter, Plaintiff suffered Injuries and Damages.

COUNT IV: STRICT PRODUCTS LIABILITY - DESIGN DEFECT

85. Plaintiff incorporates by reference all prior allegations.

86. At all relevant times, Cook designed, tested, distributed, manufactured, advertised, sold, marketed, and otherwise placed into the stream of commerce Cook IVC Filters for use by consumers, such as Plaintiff, in the United States including the State of Tennessee.

87. Cook IVC Filters were expected to, and did, reach Cook's intended consumers, handlers, and persons coming into contact with the product without substantial change in the condition in which they had researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by Cook.

88. At all times relevant, Cook IVC Filters were manufactured, designed and labeled in an unsafe, defective, and inherently dangerous condition which was dangerous for use by the public in general and Plaintiff in particular because (1) the Cook IVC Filters failed to contain adequate warnings, (2) the Cook IVC Filters are more dangerous than would be contemplated by an ordinary user, and also because the risks of the products outweigh their benefits, and (3) the Cook IVC Filter failed to comply

with their own specifications.

89. Cook IVC Filters, as researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by Cook were defective in design and formulation and unreasonably dangerous in that when they left the hands of Cook's manufacturers and/or suppliers, the foreseeable risks exceeded the alleged benefits associated with the use of Cook IVC Filters, and the devices were more dangerous than the ordinary customer would expect.

90. Physicians implanted Cook IVC Filters as instructed via the Instructions for Use and in a foreseeable manner as normally intended, recommend, promoted, and marketed by Cook.

91. Plaintiff received and utilized Defendants' IVC Filters in a foreseeable manner as normally intended, recommended, promoted, and marketed by Cook.

92. At the time Cook placed its defective and unreasonably dangerous Cook IVC Filters into the stream of commerce commercially, technologically, and scientifically feasible alternative designs were attainable and available.

93. These alternative designs would have prevented the harm resulting in Plaintiff's Injuries and Damages without substantially impairing the reasonably anticipated or intended function of Cook IVC Filters.

94. As a direct and proximate result of the defective and unreasonably dangerous condition of Cook IVC Filters, Plaintiff suffered Injuries and Damages.

COUNT V: NEGLIGENCE - DESIGN

95. Plaintiff incorporates by reference all prior allegations.

96. At the time of the design, distribution, manufacture, advertising, sale, and marketing of Cook IVC Filters, and their implantation in Plaintiff, Cook was aware that Cook IVC Filters were

designed and manufactured in a manner presenting:

a. An unreasonable risk of fracture of portions of the filters;

b. An unreasonable risk of migration of the filters and/or portions of the filters;

c. An unreasonable risk of filters tilting and/or perforating the vena cava wall; and

d. Insufficient strength or structural integrity to withstand normal placement within the human body.

97. At the time of the design, distribution, manufacture, advertising, sale, and marketing of Cook IVC Filters, and their implantation in Plaintiff, Cook also was aware that Cook IVC Filters:

a. Would be used without inspection for defects;

b. Would be used by patients with special medical conditions such as those of the Plaintiff;

c. Had previously caused serious bodily injury to its users with special medical conditions such as those of the Plaintiff;

d. Had no established efficacy;

e. Would be implanted in patients where the risk outweighed any benefit or utility of the filters;

f. Contained instructions for use and warnings that were inadequate; and

g. Required retrieval by a device that was not approved or cleared by the FDA.

98. Cook had a duty to exercise due care and avoid unreasonable risk of harm to others in the design of Cook IVC Filters.

99. Cook breached these duties by, among other things:

a. Designing and distributing a product in which it knew or should have known that the likelihood and severity of potential harm from the product exceeded the burden of taking safety measures to reduce or avoid harm;

b. Designing and distributing a product which it knew or should have known that

the likelihood and severity of potential harm from the product exceeded the likelihood of potential harm from other IVC filters available for the same purpose;

c. Failing to perform reasonable pre- and post-market testing of Cook IVC Filters to determine whether or not the products were safe for their intended use;

d. Failing to use reasonable and prudent care in the design, research, manufacture, and development of Cook IVC Filters so as to avoid the risk of serious harm associated with the use of Cook IVC Filters;

e. Advertising, marketing, promoting, and selling Cook IVC Filters for uses other than as approved and indicated in the products' labels;

f. Failing to establish an adequate quality assurance program used in the manufacturing of Cook IVC Filters; and

g. Failing to perform adequate evaluation and testing of Cook IVC Filters when such evaluation and testing would have revealed the propensity of Cook IVC Filters to cause injuries similar to those that Plaintiff suffered.

100. As a direct and proximate result of the above-described negligence in design of Cook IVC Filters, Plaintiff suffered Injuries and Damages.

COUNT VI: NEGLIGENCE - MANUFACTURE

101. Plaintiff incorporates by reference all prior allegations.

102. At all relevant times, Cook had a duty to exercise due care in the manufacturing of Cook IVC Filters.

103. Cook breached their duty by, among other things:

a. Failing to adopt manufacturing processes that would reduce the foreseeable risk of product failure;

b. Failing to use reasonable care in manufacturing the product and by producing a product that differed from their design or specifications or from other typical units from the same production line;

c. Failing to use reasonable and prudent care in the design, research, manufacture, and development of Cook IVC Filters and their manufacturing process so as to avoid the risk of serious harm associated with the use of Cook IVC Filters; and

d. Failing to establish an adequate quality assurance program used in the manufacturing of the IVC Filters

104. As a direct and proximate result of the above-described negligence in manufacture of Cook IVC Filters, Plaintiff suffered Injuries and Damages.

COUNT VII: NEGLIGENCE - FAILURE TO RECALL/RETROFIT

105. Plaintiff incorporates by reference all prior allegations.

106. At this time, all Cook IVC Filters are misbranded and adulterated by virtue of them failing to be the substantial equivalent of their predecessor device, making them subject to corrective action, including recall, in the interest of patient safety.

107. Prior to, on, and after the date of Plaintiff's implantation with Cook IVC Filters, and at all relevant times, Cook knew or reasonably should have known that Cook IVC Filters and their warnings were defective and dangerous or were likely to be dangerous when used in a reasonably foreseeable manner.

108. Prior to, on, and after the date of Plaintiff 's implantation with Cook IVC Filters and at all relevant times thereafter, Cook became aware that the defects of Cook IVC Filters resulted in Cook IVC Filters causing injuries similar to those Plaintiff suffered.

109. Reasonable manufacturers and distributors under the same or similar

110. Circumstances would have recalled or retrofitted Cook IVC Filters, and would thereby have avoided and prevented harm to many patients, including Plaintiff.

111. In light of this information and Cook's knowledge described above, Cook had a duty to recall and/or retrofit Cook IVC Filters.

112. Cook breached its duty to recall and/or retrofit Cook IVC Filters.

113. As a direct and proximate result of Cook's negligent failure to recall or retrofit, Plaintiff

suffered Injuries and Damages.

COUNT VIII: NEGLIGENCE - FAILURE TO WARN

114. Plaintiff incorporates by reference all prior allegations.

114. At all relevant times, Cook knew or should have known that Cook IVC Filters were defective and dangerous or were likely to be dangerous when used in a reasonable foreseeable manner.

115. Such danger included the propensity of Cook IVC Filters to cause injuries and death similar to those suffered by Plaintiff. At all relevant times, Cook also knew or reasonably should have known that the users of Cook IVC Filters, including Plaintiff, would not realize or discover on their own the dangers presented by Cook IVC Filters.

116. Reasonable manufacturers and reasonable distributors, under the same or similar circumstances as those of Cook prior to, on, and after the date of Plaintiff was implanted with the Cook Gunther Tulip® Filter, would have warned of the dangers presented by Cook IVC Filters, or instructed on the safe use of Cook IVC Filters.

117. Prior to, on, and after the date of Plaintiff's use of the IVC Filters, Cook had a duty to adequately warn of the dangers presented by Cook IVC Filters and/or instruct on the safe use of Cook IVC Filters.

118. Cook breached these duties by failing to provide adequate warnings to Plaintiff communicating the information and dangers described above and/or providing instruction for safe use of Cook IVC Filters.

119. As a direct and proximate result of Cook's negligent failure to warn, Plaintiff suffered Injuries and Damages.

COUNT IX: NEGLIGENT MISREPRESENTATION

120. Plaintiff incorporates by reference all prior allegations.

121. Prior to, on, and after the dates during which Plaintiff was implanted with the Cook Gunther Tulip® IVC Filter, Cook negligently and carelessly represented to Plaintiff, Plaintiff's treating physicians, and the general public that Cook IVC Filters were safe, fit, and effective for use.

122. These representations were untrue.

123. Cook owed a duty in all of its undertakings, including the dissemination of information concerning its IVC filters, to exercise reasonable care to ensure that it did not in those undertakings create unreasonable risks of personal injury to others.

124. Cook disseminated to health care professionals and consumers through published labels, labeling, marketing materials, and otherwise information concerning the properties and effects of Cook IVC Filters with the intention that health care professionals and consumers would rely upon that information in their decisions concerning whether to prescribe and use Cook IVC Filters.

125. Cook, as medical device designers, manufacturers, sellers, promoters and/or distributors, knew or should reasonably have known that health care professionals and consumers, in weighing the potential benefits and potential risks of prescribing or using Cook IVC Filters, would rely upon information disseminated and marketed by Cook to them regarding the Cook IVC Filters.

126. Cook failed to exercise reasonable care to ensure that the information they disseminated to health care professionals and consumers concerning the properties and effects of Cook IVC Filters was accurate, complete, and not misleading and, as a result, disseminated information to health care professionals and consumers that was negligently and materially inaccurate, misleading, false, and unreasonably dangerous to consumers such as Plaintiff.

127. Cook, as designers, manufacturers, sellers, promoters, and/or distributors, also knew or

reasonably should have known that patients receiving Cook IVC Filters as recommended by health care professionals in reliance upon information disseminated by Cook as the manufacturer/distributor of Cook IVC Filters would be placed in peril of developing the serious, life-threatening, and life-long injuries including, but not limited to, tilting, migration, perforation, fracture, lack of efficacy, and increased risk of the development of blood clots, if the information disseminated and relied upon was materially inaccurate, misleading, or otherwise false.

128. Cook had a duty to promptly correct material misstatements it knew others were relying upon in making healthcare decisions.

129. Cook failed in each of these duties by misrepresenting to Plaintiff and the medical community the safety and efficacy of Cook IVC Filters and failing to correct known misstatements and misrepresentations.

130. As a direct and proximate result of Cook's negligent misrepresentations, Plaintiff suffered Injuries and Damages.

COUNT X: NEGLIGENCE *PER SE*

(Violations of 21 U.S.C. §§321, 331, 352 and 21 C.F.R. §§1.21, 801, 803, 807, 820)

131. Plaintiff incorporates by reference all prior allegations.

132. At all times herein mentioned, Cook was subject to a variety of federal, state, and local laws, rules, regulations and ordinances, including the Federal Food, Drug, and Cosmetic Act ("FFDCA") and its applicable regulations, concerning the manufacture, design, testing, production, processing, assembling, inspection, research, promotion, advertising, distribution, marketing, promotion, labeling, packaging, preparation for use, consulting, sale, warning, post-sale warning, and other communications of the risks and dangers of Cook IVC Filters.

133. By reason of its conduct as alleged herein, Cook violated provisions of statutes and

regulations, including but not limited to:

a. FFDCA, 21 U.S.C. §§331 and 352, by misbranding Cook IVC Filters;

b. FFDCA, 21 U.S.C. § 321, by making statements and/or representations via word, design, device, or any combination thereof failing to reveal material facts with respect to the consequences that may result from the use of Cook IVC Filters to which the labeling and advertising relates;

c. 21 C.F.R. § 1.21, by misleading *its* consumers and patients by concealing material facts in light of representations made regarding safety and efficacy of its Cook IVC Filters;

d. 21 C.F.R. § 801, by mislabeling Cook IVC Filters as to safety and effectiveness of its products and by failing to update its label to reflect post-marketing evidence that Cook IVC Filters were associated with an increased risk of injuries due to tilting, fracture, migration and perforation;

e. 21 C.F.R. §§801.109 and 801.4, by learning that Cook IVC Filters were adulterated and misbranded and failing to correct and recall the devices;

f. 21 C.F.R. § 803, by not maintaining accurate medical device reports regarding adverse events of tilting, fracture, migration and perforation and/or misreporting these adverse events maintained via the medical device reporting system;

g. 21 C.F.R. § 807, by failing to notify the FDA and/or the consuming public when its Cook IVC Filters were no longer substantially equivalent with regard to safety and efficacy with regard to post-marketing adverse events and safety signals;

h. 21 C.FR. § 820, by failing to maintain adequate quality systems regulation including, but not limited to, instituting effective corrective and preventative actions;

i. 21 CPR 201.128, by promoting each of their subject devices off-label and for conditions, purposes and uses beyond their labeled and intended uses; and

j. 210 CPR 801.4, by their knowledge of off-label uses of their devices for unintended and unlabeled conditions, purposes and uses, and failing as required to provide adequate labeling which accords with such unlabeled and unintended uses.

134. These statutes, rules and regulations, along with those listed in Count XIV, are designed to protect the health, safety, and well-being of consumers like Plaintiff.

135. Cook's violation of these statutes, rules and regulations, as well as those detailed in Count XIV, constitutes negligence *per se.*

136. As a direct and proximate result of Cook's negligence *per se,* Plaintiff suffered 18 Injuries and Damages.

COUNT XI: BREACH OF EXPRESS WARRANTY

137. Plaintiff incorporates by reference all prior allegations.

138. Plaintiff, though her medical providers, purchased Cook IVC Filters from Cook.

139. At all relevant times, Cook was a merchant of goods of the kind including medical devices and vena cava filters (i.e., Cook IVC Filters).

140. At the time and place of sale, distribution, and supply of Cook IVC Filters to Plaintiff (and to other consumer and the medical community), Cook expressly represented and warranted that Cook IVC Filters were safe; that they were well-tolerated, efficacious, fit for their intended purpose, and of marketable quality; that they did not produce any unwarned-of dangerous side effects; and that they were adequately tested.

141. At the time of Plaintiff's purchase from Defendants, Cook IVC Filters were not in a merchantable condition, and Cook breached its expressed warranties, in that Cook IVC:

a. Were designed in such a manner so as to be prone to an unreasonably high incidence of fracture, perforation of vessels and organs, and/or migration;

b. Were designed in such a manner so as to result in an unreasonably high incidence of injury to the vessels and organs of its purchaser;

c. Were manufactured in such a manner that the exterior surface of the filter was inadequately, improperly, and inappropriately constituted, causing the device to weaken and fail;

d. Were unable to be removed at any time during a person's life;

e. Were not efficacious in the prevention of pulmonary emboli;

f. Carried a risk of use outweighed any benefit; and

g. Were not self-centering.

242. As a direct and proximate result of Cook's breach of express warranty, Plaintiff suffered Injuries and Damages.

COUNT XII: BREACH OF IMPLIED WARRANTY

243. Plaintiff incorporates by reference all prior allegations.

244. Cook impliedly warranted that Cook IVC Filters were of merchantable quality and safe and fit for the use for which Cook intended them, and Plaintiff in fact used them.

245. Cook breached its implied warranties by:

a. Failing to provide adequate instruction that a manufacturer exercising reasonable care would have provided concerning the likelihood that Cook IVC Filters would cause harm;

b. Manufacturing and/or selling Cook IVC Filters when those filters did not conform to representations made by Cook when they left Cook's control;

c. Manufacturing and/or selling Cook IVC Filters that were more dangerous than an ordinary consumer would expect when used in an intended or reasonably foreseeable manner;

d. Manufacturing and/or selling Cook IVC Filters that carried foreseeable risks associated with the Cook IVC Filter design or formulation which exceeded the benefits associated with that design;

e. Manufacturing and/or selling Cook IVC Filters when they deviated in a material way from the design specifications, formulas, or performance standards or from otherwise identical units manufactured to the same design specifications, formulas, or performance standards; and

f. Impliedly representing that its filters would be effective in the prevention of pulmonary emboli.

246. As a direct and proximate result of Cook's breach of its implied warranty, Plaintiff suffered Injuries and Damages.

COUNT XIII: FRAUDULENT MISREPRESENTATION

247. Plaintiff incorporates by reference all prior allegations.

248. At all times relevant to this cause, and as detailed above, Cook intentionally provided Plaintiff, Plaintiff's physicians, the medical community, and the public at large with false or inaccurate information. Cook also omitted material information and intentionally misrepresented existing material facts concerning Cook IVC Filters, including, but not limited to, misrepresentations regarding the following topics:

a. The safety of the Cook IVC Filters;

b. The efficacy of the Cook IVC Filters;

c. The rate of failure of the Cook IVC Filters;

d. The pre-market testing of the Cook IVC Filters;

e. The approved uses of the Cook IVC Filters; and

f. The ability to retrieve the device at any time over a person 's life.

249. The information Cook distributed to the public, the medical community, and Plaintiff was in the form of reports, press releases, advertising campaigns, labeling materials, print advertisements, commercial media containing material representations, and instructions for use, as well as through their officers, directors, agents, and representatives.

250. These materials contained false and misleading material representations, which included: that Cook IVC Filters were safe and fit when used for their intended purpose or in a reasonably foreseeable manner; that they did not pose dangerous health risks in excess of those associated with the use of other similar IVC filters; that any and all side effects were accurately reflected in the warnings; and that they were adequately tested to withstand normal placement within

the human body.

251. Cook made the foregoing misrepresentations knowing that they were false or without reasonable basis, knowledge of the falsity of the representations. These materials included instructions for use and a warning document that was included in the package of Cook IVC Filters that were implanted in Plaintiff.

252. Cook's intent and purpose in making these misrepresentations was to deceive and defraud the public and the medical community, including Plaintiff's health care providers; to gain the confidence of the public and the medical community, including Plaintiff's health care providers, to falsely assure the public and the medical community; of the quality of Cook IVC Filters and their fitness for use, and to induce the public and the medical community, including Plaintiff's healthcare providers to request, recommend, prescribe, implant, purchase, and continue to use Cook IVC Filters, all in reliance on Cook's misrepresentations.

253. The foregoing representations and omissions by Cook were false.

254. Cook IVC Filters are not safe, fit, and effective for human use in their intended and reasonably foreseeable manner.

255. Further, the use of Cook IVC Filters is hazardous to the users' health, and Cook IVC Filters have a serious propensity to cause users to suffer serious injuries, including without limitation the injuries Plaintiff suffered.

256. Finally, Cook IVC Filters have a statistically significant higher rate of failure and injury than do other comparable IVC filters.

257. In reasonable reliance upon the false and negligent misrepresentations and omissions made by Cook, Plaintiff and Plaintiff's health care providers were induced to, and did use Cook IVC Filters, thereby causing Plaintiff to sustain severe and permanent personal injuries and death.

258. Cook knew and had reason to know that Plaintiff, Plaintiff's health care providers, and the general medical community did not have the ability to determine the true facts intentionally and/or negligently concealed and misrepresented by Cook, and would not have prescribed and implanted Cook IVC Filters if the true facts regarding Cook IVC Filters had not been concealed and misrepresented by Cook.

259. Cook had sole access to material facts concerning the defective nature of the products and their propensities to cause serious and dangerous side effects in the form of dangerous injuries and damages to persons who were implanted with Cook IVC Filters.

260. At the time Cook failed to disclose and intentionally misrepresented the foregoing facts, and at the time Plaintiff reasonably used Cook IVC Filters, Plaintiff and Plaintiff's health care providers were unaware of Cook's misrepresentations and omissions.

261. As a direct and proximate result of Cook's fraudulent misrepresentations, Plaintiff suffered Injuries and Damages.

COUNT XIV: FRAUDULENT CONCEALMENT

262. Plaintiff incorporates by reference all prior allegations.

263. In marketing and selling Cook IVC Filters, Cook concealed material facts from Plaintiff and Plaintiff's healthcare providers.

264. These concealed material facts include, but are not limited to:

a. Cook IVC Filters were unsafe and not fit when used for their intended purpose or in a reasonably foreseeable manner;

b. Cook IVC Filters posed dangerous health risks in excess of those associated with the use of other similar IVC filters;

c. That there were additional side effects related to implantation and use of Cook IVC Filters that were not accurately and completely reflected in the warnings associated with Cook IVC Filters; and

d. That Cook IVC Filters were not adequately tested to withstand normal placement within the human body.

265. Plaintiff and Plaintiff's healthcare providers were not aware of these and other facts concealed by Cook.

266. In concealing these and other facts, Cook intended to deceive Plaintiff and Plaintiff's healthcare providers.

267. Plaintiff and Plaintiff's healthcare providers were ignorant of and could not reasonably discovered the facts Cook fraudulently concealed and reasonably and justifiable and reasonably relied on Cook's representations concerning the supposed safety and efficacy of Cook IVC Filters.

268. As a direct and proximate result of Defendants' fraudulent concealment of material facts, Plaintiff suffered Injuries and Damages.

COUNT XV: VIOLATIONS OF STATE LAW PROHIBITING CONSUMER FRAUD AND UNFAIR DECEPTIVE TRADE PRACTICES

269. Plaintiff incorporates by reference all prior allegations.

274. Cook had a statutory duty to refrain from unfair or deceptive acts or practices in the sale and promotion of Cook IVC Filters.

270. Cook knowingly, deliberately, willfully, and/or wantonly engaged in unfair, unconscionable, deceptive, fraudulent, and misleading acts or practices in violation of all states' consumer protection laws identified below.

271. Through its false, untrue, and misleading promotion of Cook IVC Filters, Cook induced Plaintiff to purchase and/or pay for the purchase of Cook IVC Filters.

272. Cook misrepresented the alleged benefits and characteristics of Cook IVC Filters; suppressed, omitted, concealed, and failed to disclose material information concerning known adverse effects of Cook IVC Filters; misrepresented the quality and efficacy of Cook IVC Filters as compared

to much lower-cost alternatives; misrepresented and advertised that Cook IVC Filters were of a particular standard, quality, or grade that they were not; misrepresented Cook IVC Filters in such a manner that later, on disclosure of the true facts, there was a likelihood that Plaintiff would have opted for an alternative IVC filter or method of preventing pulmonary emboli.

273. Cook's conduct created a likelihood of, and in fact caused, confusion and misunderstanding.

274. Cook's conduct misled, deceived, and damaged Plaintiff, and Cook's fraudulent, misleading and deceptive conduct was perpetrated with an intent that Plaintiff reasonably relied on said conduct by purchasing and/or paying for purchases of Cook IVC Filters.

275. Moreover, Cook knowingly took advantage of Plaintiff, who was unable to protect their own interests due to ignorance of the handful adverse effects of Cook IVC Filters.

276. Cook's conduct was willful, intentional, outrageous, immoral, unethical, oppressive, unscrupulous, unconscionable, and substantially injurious to Plaintiff and offends the public conscience.

277. Plaintiff purchased Cook's IVC Filters primarily for personal, family, or household purposes.

278. As a result of Cook's violative conduct, Plaintiff purchased and/or paid for purchases of Cook IVC Filters that were not made for resale.

279. Cook engaged in unfair competition or deceptive acts or practices in violation of Tenn. Code Ann. § 47-18-104, *et seq.*

280. As a direct and proximate result of Cook's violations of these statutes, Plaintiff suffered Injuries and Damages and seek all available damages under Tennessee law.

PUNITIVE DAMAGES ALLEGATIONS

281. Plaintiff incorporates by reference all prior allegations.

282. At all times material hereto, Cook knew or should have known that Cook IVC Filters were unreasonably dangerous with respect to the risk of tilt, fracture, migration, and/or perforation.

283. At all times material hereto, Cook attempted to misrepresent and did knowingly misrepresent facts concerning the safety of Cook IVC Filters.

284. Cook's misrepresentations included knowingly withholding material information from the medical community and the public, including Plaintiff's physicians, concerning the safety of its Cook IVC Filters.

285. Cook's conduct, alleged throughout this Complaint, was willful, wanton, and undertaken with a conscious indifference and disregard to the consequences that consumers of their products faced, including Plaintiff and her decedents.

286. At all times material hereto, Cook knew and recklessly disregarded the fact that Cook IVC Filters have an unreasonably high rate of tilt, fracture, migration, and/or perforation.

287. Notwithstanding the foregoing, Cook continued to market Cook IVC Filters aggressively to consumers, including Plaintiff, without disclosing the aforesaid side effects.

288. Cook knew of its Cook IVC Filters' lack of warnings regarding the risk of fracture, migration, and/or perforation, but intentionally concealed and/or recklessly failed to disclose that risk and continued to market, distribute, and sell its filters without said warnings so as to maximize sales and profits at the expense of the health and safety of the public, including Plaintiff, in conscious disregard of the foreseeable harm caused by Cook IVC Filters.

289. Cook's intentional and/or reckless failure to disclose information deprived Plaintiff's physicians of necessary information to enable them to weigh the true risks of using Cook IVC Filters against its benefits.

290. Cook's conduct is reprehensible, evidencing an evil hand guided by an evil mind and

was undertaken for pecuniary gain in reckless and conscious disregard for the substantial risk of death and physical injury to consumers, including Plaintiff and her decedents.

291. Such conduct justifies an award of punitive or exemplary damages in an amount sufficient to punish Cook's conduct and deter like conduct by Cook and other similarly situated persons and entities in the future.

TOLLING OF THE LIMITATIONS PERIOD

292. The Cook Defendants, through their affirmative misrepresentations and omissions, actively concealed from the Plaintiff and Plaintiff's healthcare providers the true and significant risks associated with Cook Filters.

293. As a result of the Cook Defendants' actions, Plaintiff and her prescribing physicians were unaware, and could not have reasonably known or have learned through reasonable diligence, that Plaintiff had been exposed to the risks identified in her Complaint, and that those risks were the result of Defendants' acts, omissions, and misrepresentations.

294. Accordingly, no limitations period ought to accrue until such time as Plaintiff knew or reasonably should have known of some causal connection between Plaintiff being implanted with a Cook Filter and the harm Plaintiff suffered as a result.

295. Additionally, the accrual and running of any applicable statute of limitations have been tolled by reason of the Cook Defendants' fraudulent concealment.

296. Additionally, the Cook Defendants are equitably estopped from asserting any limitations defense by virtue of their fraudulent concealment and other misconduct as described.

297. Additionally, the limitations period ought to be tolled under principles of equitable tolling.

298. In addition, no limitations period ought to accrue until such time as Plaintiff knew or

reasonably should have known that Plaintiff was implanted with a Cook Filter and that the harm Plaintiff suffered was a result from the Cook Filter.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff pray for judgment against Defendants, as appropriate to each cause of action alleged and as appropriate to the standing of Plaintiff, as follows, including compensatory damages without limitation:

a. Physical pain and suffering in the past and which, in reasonable probability, Plaintiff, BARBARA C. RADFORD will continue to suffer in the future;

b. Physical impairment and incapacity in the past and which, in reasonable probability, Plaintiff, BARBARA C. RADFORD will continue to suffer in the future;

c. Mental anguish in the past and which, in reasonable probability, Plaintiff, BARBARA C. RADFORD will sustain in the future;

d. Reasonable and necessary medical expenses for treatment received in the past, and, based upon reasonable medical probability, the reasonable medical expenses Plaintiff, BARBARA C. RADFORD will incur in the future;

e. Disfigurement in the past and which, in reasonable probability, Plaintiff, BARBARA C. RADFORD will continue to suffer in the future;

f. Punitive damages;

g. Plaintiff be awarded full, fair, and complete recovery for all claims and causes of action relevant to this action;

h. Plaintiff be awarded all appropriate costs, reasonable attorney's fees, expenses, and prejudgment and post-judgment interest pursuant to the laws of the State of Tennessee as authorized by law on the judgements entered in Plaintiff's behalf; and

i. Such other relief, in law or in equity the court deems just and proper.

DEMAND FOR JURY TRIAL

Plaintiff respectfully requests trial by jury in the above case as to all issues.

Dated: January 5, 2021

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